

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

ZERO SPOT LOTION

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydroquinone 2% w/w

3 PHARMACEUTICAL FORM

Topical Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For Topical Administration

For reducing hyperpigmentation of skin, such as persistent freckles and brown marks (lentiginos) and irregular pigmentation of negroid skin.

4.2 Posology and method of administration

Adults and Elderly: Apply twice daily after washing, until pigmentation has been reduced (depending on skin type, for 6-16 weeks). Then twice weekly.

Children: Not for use on children, unless under the direction of a physician.

4.3 Contraindications

Known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Not suitable for red marks.

Do not use on broken skin or near eyes.

For external use only.

Keep medicines away from children.

Discontinue if eczema or irritation occurs, or if darkening reoccurs during treatment.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

No undesirable effects known during pregnancy or lactation but contact between treated skin and infants is to be avoided.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Irritation and subsequent hypersensitivity have been observed but are rare for creams at less than 5% Hydroquinone. Ochronosis and pigmented colloid milium have been reported following extended use of stronger creams in a high sunshine climate(South

Africa). Such severe effects are preceded by redarkening of the skin and follow continual administration.

4.9 Overdose

None known as regards topical application. If accidentally ingested, treat symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hydroquinone interferes with the production of new melanocytes and hence the bleaching effect on pigmented skin progresses slowly and evenly.

5.2 Pharmacokinetic properties

Effects on pigmented skin are normally observed by 6 weeks from initiation of the hydroquinone treatment. The time varies according to skin type.

5.3 Preclinical safety data

No additional information to that already included elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS 6.1 List of excipients

Sodium lauryl sulphate (Ph. Eur.), propylene glycol (Ph. Eur.), disodium edetate (Ph. Eur.), ascorbic acid (Ph. Eur.), sodium metabisulphite (Ph. Eur.), glyceryl monostearate (Ph. Eur.), isopropyl myristate (Ph. Eur.), cetyl esters wax (NF), cetostearyl alcohol (Ph. Eur.), propyl parahydroxybenzoate (Ph. Eur.), potable water.

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

None

6.5 Nature and contents of container

Epoxy-resin lined, collapsible, aluminium tubes with polyethylene closure, containing 50g cream.

6.6 Special precautions for disposal

Wash hands after use

7 MARKETING AUTHORISATION HOLDER

Tosh Pharmaceuticals Limited -

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8 MARKETING AUTHORISATION NUMBER(S)

FDA/SD.245-091755

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

30/09/2024

10 DATE OF REVISION OF THE TEXT

11/10/2025